August 22, 2025

Access Bio, Inc.
Sung Jang
Senior Manager of Regulatory Affairs
7 Fitzgerald Ave.
Monroe Township, New Jersey 08831

Re: K251604
Trade/Device Name: CareSuperb COVID-19/Flu A&B Antigen Combo Home Test
Regulation Number: 21 CFR 866.3987
Regulation Name: Multi-Analyte Respiratory Virus Antigen Detection Test
Regulatory Class: Class II
Product Code: SCA
Dated: May 26, 2025
Received: May 27, 2025

Dear Sung Jang:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JOSEPH BRIGGS -S

Joseph Briggs, Ph.D.
Deputy Director
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251604

Device Name
CareSuperb COVID-19/Flu A&B Antigen Combo Home Test

Indications for Use *(Describe)*
The CareSuperb COVID-19/Flu A&B Antigen Combo Home Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigens directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. Symptoms of respiratory infections due to SARS-CoV-2 and influenza can be similar. This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older.

All negative results are presumptive and should be confirmed with an FDA-cleared molecular assay when determined to be appropriate by a healthcare provider. Negative results do not rule out infection with influenza, SARS-CoV-2, or other pathogens.

Individuals who test negative and experience continued or worsening respiratory symptoms, such as fever, cough, and/or shortness of breath, should seek follow up care from their healthcare provider.

Positive results do not rule out co-infection with other respiratory pathogens and therefore do not substitute for a visit to a healthcare provider for appropriate follow-up.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

Access Bio, Inc.
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510(k) Summary

Date Prepared: August 22, 2025

1. Submitter Information

Submitter	Access Bio, Inc. 7 Fitzgerald Ave. Monroe Township, NJ 08831 Tel.: +1-732-873-4040
Contact Person	Sung Jang, Senior Manager of Regulatory Affairs Email: sajang@accessbio.net

2. Device Information

Trade Name	CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test
Common Name	Multi-analyte respiratory virus antigen detection test
Classification	Class II
Classification Name	Multi-Analyte Respiratory Virus Antigen Detection Test
Product Code	SCA
Regulation Number	21 CFR 866.3987

3. Legally Marketed Predicate Device

Trade Name	WELLlife COVID-19/Influenza A&B Home Test / WELLlife COVID-19/Influenza A&B Antigen Test
Manufacturer	Wondfo USA Co., Ltd.
510(k) Number	K243256

4. Device Description

The CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test is a lateral flow immunoassay intended for the qualitative detection and differentiation of SARS-CoV-2 nucleocapsid antigen, Influenza A nucleoprotein antigen, and Influenza B nucleoprotein antigen from anterior nasal swab specimens.

The CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test utilizes an adaptor-based lateral flow assay platform integrating a conjugate wick filter to facilitate sample processing. Each test cassette contains a nitrocellulose membrane with immobilized capture antibodies for SARS-CoV-2, Influenza A, Influenza B, and internal control. Following specimen application to the sample port, viral antigens, if present, bind to labeled detection antibodies embedded in the conjugate wick filter. The resulting immune complexes migrate along the test strip and are captured at the respective test lines (C19 for SARS-CoV-2, A for Influenza A, and B for Influenza B), forming visible colored lines. A visible control line (Cont) confirms proper sample migration and test validity. The absence of a control line invalidates the test result.

Each kit includes a single-use test cassette, assay buffer dropper vial, nasal swab, and Quick Reference Instructions (QRI). Test results are visually interpreted 10 minutes after swab removal.

4.1. Indications for Use / Intended Use

The CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. Symptoms of respiratory infections due to SARS-CoV-2 and influenza can be similar. This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older.

All negative results are presumptive and should be confirmed with an FDA-cleared molecular assay when determined to be appropriate by a healthcare provider. Negative results do not rule out infection with influenza, SARS-CoV-2, or other pathogens.

Individuals who test negative and experience continued or worsening respiratory symptoms, such as fever, cough, and/or shortness of breath, should seek follow up care from their healthcare provider.

Positive results do not rule out co-infection with other respiratory pathogens and therefore do not substitute for a visit to a healthcare provider for appropriate follow-up.

5. Comparison with Predicate Device

The CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test is substantially equivalent in fundamental technology and principles to the legally marketed predicate device, the Wondfo WELLlife COVID-19/Influenza A&B Home Test / WELLlife COVID-19/Influenza A&B Antigen Test (K243256). The comparison of the predicate and proposed devices is summarized in Table 1.

Table 1. Comparison of Predicate and Proposed Devices with Predicate Device

Contents	Predicate Device	Proposed Device
Manufacturer	Wondfo USA Co., Ltd.	Access Bio, Inc.
Proprietary Name	WELLlife COVID-19/Influenza A&B Home Test / WELLlife COVID-19/Influenza A&B Antigen Test (K243256)	CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test
Intended Use/ Indications for Use	WELLlife™ COVID-19 / Influenza A&B Home Test: The WELLlife™ COVID-19 / Influenza A&B Home Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A, and influenza B nucleoprotein antigens and SARS-CoV2 nucleocapsid antigen directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. Symptoms of respiratory infections due to SARS-CoV-2 and influenza can be similar. This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older. All negative results are presumptive and should be confirmed with an FDA-cleared molecular assay when determined to be appropriate by a healthcare provider. Negative results do not rule out infection with influenza, SARS-CoV-2 or other pathogens.	The CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid protein directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. Symptoms of respiratory infections due to SARS-CoV-2 and influenza can be similar. This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older. All negative results are presumptive and should be confirmed with an FDA-cleared molecular assay when determined to be appropriate by a healthcare provider. Negative results do not rule out infection with influenza, SARS-CoV-2, or other pathogens.

Contents	Predicate Device	Proposed Device
Intended Use/ Indications for Use	Individuals who test negative and experience continued or worsening respiratory symptoms, such as fever, cough and/or shortness of breath, should seek follow-up care from their healthcare provider. Positive results do not rule out co-infection with other respiratory pathogens, and therefore do not substitute for a visit to a healthcare provider or appropriate follow-up. WELLlife™ COVID-19 / Influenza A&B Antigen Test: The WELLlife™ COVID-19 / Influenza A&B Antigen Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A, and influenza B nucleoprotein antigens and SARS-CoV2 nucleocapsid antigen directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. Symptoms of respiratory infections due to SARS-CoV-2 and influenza can be similar. This test is for use by individuals aged 14 years or older testing themselves, or adults testing aged 2 years or older. All negative results are presumptive and should be confirmed with an FDA-cleared molecular assay when determined to be appropriate by a healthcare provider. Negative results do not rule out infection with influenza, SARS-CoV-2, or other pathogens. Individuals who test negative and experience continued or worsening respiratory symptoms, such as fever, cough and/or shortness of breath, should seek follow-up care from their healthcare providers. Positive results do not rule out co-infection with other respiratory pathogens. Test results should not be used as the sole basis for treatment or other patient management decisions.	Individuals who test negative and experience continued or worsening respiratory symptoms, such as fever, cough, and/or shortness of breath, should seek follow up care from their healthcare provider. Positive results do not rule out co-infection with other respiratory pathogens and therefore do not substitute for a visit to a healthcare provider for appropriate follow-up.
Product Code	SCA	SCA
Regulation Number	21 CFR 866.3987	21 CFR 866.3987
Regulatory Class	Class II	Class II
Common Name	Multi-Analyte Respiratory Virus Antigen Detection Test	Multi-Analyte Respiratory Virus Antigen Detection Test
Test Principle	Lateral flow immunoassay	Lateral flow immunoassay
Assay Type	Qualitative	Qualitative
Intended Users	Over-the-counter lay users or professional use	Over-the-counter lay users
Intended Use Population	Self-testing for symptomatic individuals aged 14 years or older and adults testing individuals aged 2 years and older within 4 days post symptom onset.	Self-testing for symptomatic individuals aged 14 years or older and adults testing individuals aged 2 years and older within 4 days post symptom onset.
Assay Target	Influenza A nucleoprotein antigen, Influenza B	Influenza A nucleoprotein antigen, Influenza B

Contents	Predicate Device	Proposed Device
	nucleoprotein antigen and/or SARS-CoV-2 nucleocapsid protein antigens	nucleoprotein antigen and/or SARS-CoV-2 nucleocapsid protein antigens
Specimen Type	Direct anterior nasal swab specimen	Direct anterior nasal swab specimen
Result Interpretation	Visually read	Visually read
Control	Internal control	Internal control
Storage Condition	2-30°C	2-30°C
Development Time	10-20 minutes	10-15 minutes
Device Type	Test cartridge (cassette)	Test cartridge (cassette with a sample port)

6. Test Principle

The CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test is lateral flow immunochromatographic assays intended for the qualitative detection and differentiation of SARS-CoV-2 nucleocapsid antigen, Influenza A nucleoprotein antigen, and Influenza B nucleoprotein antigen from anterior nasal swab specimens. The tests utilize an adaptor-based lateral flow design featuring a cylindrical conjugate wick filter to enhance sample processing and improve analytical sensitivity. The system enables efficient sample and conjugate interaction and promotes continuous migration of analyte–antibody complexes toward the detection zone.

Following sample collection, the swab is inserted into the sample port, and assay buffer is applied to release viral antigens. The extracted sample migrates through the conjugate wick, where labeled antibodies form immune complexes if target antigens are present. These complexes are captured by specific immobilized antibodies on a nitrocellulose membrane, producing visible colored test lines corresponding to SARS-CoV-2 (C19), Influenza A (A), and Influenza B (B). A visible control line (Cont) indicates proper assay performance. Test results are visually interpreted 10 minutes after swab removal.

7. Performance Data

To establish the performance characteristics of the CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test to the predicate device, following studies were conducted:

7.1. Analytical Performance

1) Precision

A precision study was evaluated in two different studies conducted at single internal site each using three (3) lots of test kits and two (2) operators.

Study 1 was conducted using test samples prepared at three (3) different concentrations of heat inactivated SARS-CoV-2 B.1.1.529, live Flu A: H1N1pdm09/A/Indiana/02/2020, and live Flu B: Victoria/New Hampshire /01/2021 spiked into pooled negative swab matrix (PNSM) to prepare the following test sample panel members: a negative sample, low positive sample (1x co-spike LoD of each analyte), and moderate positive samples (3x co-spike LoD of each analyte). Samples were blinded and randomized before allotting them to the operators. 50µL of each sample was applied to dry nasal swabs and processed per the IFU of the candidate device. All panel members were tested in triplicate with 3 device lots, each in 2 runs per day for each of 2 operators, and the study was conducted for 10 days (i.e., 1 site x 3 lots x 2 operators x 2 runs per day with 3 replicates each x 10 days). 360 results were obtained for each panel member. All replicates prepared at 1xLoD and 3xLoD, demonstrated above 95% agreement across the operators, lots, days and runs test.

Study 2 was performed using a negative sample without any of the analytes, and low positive samples prepared at the 0.75x LoD for each analyte to demonstrate potential lot variability. Two operators tested the samples above in a randomized and blinded manner each using three different lots in a total of 2 runs/operators and across 3 non-consecutive days (i.e., 3 replicates × 2 runs/day × 3 days × 2 operators = 36 sample replicates/lot). The precision of the test was assessed by

repeating tests over multiple days, by different users, and across three product lots. A summary of the lot-to-lot precision results is provided in Table 2.

Table 2. Summary of Lot-to-lot Precision Results

Sample Type	Analyte	# of Positive / # of Replicates			% Positive	95% CI
		Lot 1	Lot 2	Lot 3		
Negative	NSM	0/156	0/156	0/156	0	97.6-100%
Positive (0.75X LoD)	SARS-CoV-2	32/36	29/36	31/36	85.2	77.2-90.1%
	Flu A	32/36	31/36	33/36	88.9	81.6-93.5%
	Flu B	32/36	32/36	34/36	90.7	83.8-94.9%
Positive (1X LoD)	SARS-CoV-2	120/120	120/120	117/120	99.2	97.6-99.7%
	Flu A	120/120	120/120	117/120	99.2	97.6-99.7%
	Flu B	120/120	120/120	119/120	99.7	98.4-100%
Positive (3X LoD)	SARS-CoV-2	120/120	120/120	120/120	100	98.9-100%
	Flu A	120/120	120/120	120/120	100	98.9-100%
	Flu B	120/120	120/120	120/120	100	98.9-100%

2) Limit of Detection (LoD)

Single Analyte LoD

The sensitivity of the CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test was established by evaluating different concentrations of 2 strains of inactivated SARS-CoV-2 and multiple strains of live influenza A and influenza B. The viruses were diluted in pooled negative swab matrix (PNSM) to generate virus dilutions for testing. The lowest detectable concentration that generated ≥95% positive detection rate was determined as the LoD through serial dilution and confirmed with repeated testing. The confirmed LoDs for the CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test are summarized in Table 3.

Table 3. Confirmatory LoDs

Virus Strain		Stock Strain (Titer Unit/mL)	LoD		Result Agreement (%)
			Titer Unit/mL	Titer Unit/Swab	
SARS-CoV-2	SARS-Related Coronavirus 2, Isolate USA-WA1/2020	7.9×10^5 $TCID_{50}$/mL	2.63×10^2 $TCID_{50}$/mL	1.32×10^1 $TCID_{50}$/Swab	100
	SARS-Related Coronavirus 2, Isolate hCoV-19/USA/GA-EHC-2811C/2021 (Lineage B.1.1.529; Omicron Variant)	1.5×10^6 $TCID_{50}$/mL	1.5×10^2 $TCID_{50}$/mL	7.50×10^0 $TCID_{50}$/Swab	100
Influenza A	A/Brisbane/59/2007 (H1N1)	1.6×10^{10} $CEID_{50}$/mL	1.6×10^7 $CEID_{50}$/mL	8.00×10^5 $CEID_{50}$/Swab	100
	A/Hawaii/66/2019 (H1N1) pdm09	7.4×10^9 $CEID_{50}$/mL	7.4×10^6 $CEID_{50}$/mL	3.70×10^5 $CEID_{50}$/Swab	100
	A/Indiana/02/2020 (H1N1) pdm09	9.7×10^8 $CEID_{50}$/mL	9.7×10^5 $CEID_{50}$/mL	4.85×10^4 $CEID_{50}$/Swab	100
	A/California/55/2020 (H3N2)	3.5×10^8 FFU/mL	1.17×10^5 FFU/mL	5.83×10^3 FFU/Swab	100

Virus Strain		Stock Strain (Titer Unit/mL)	LoD		Result Agreement (%)
			Titer Unit/mL	Titer Unit/Swab	
	A/Delaware/01/2021 (H3N2)	3.1×10^7 FFU/mL	3.1×10^4 FFU/mL	1.55×10^3 FFU/Swab	100
Influenza B	B/New Hampshire/01/2021 (Victoria Lineage)	1.3×10^6 $TCID_{50}$/mL	4.33×10^2 $TCID_{50}$/mL	2.17×10^1 $TCID_{50}$/Swab	100
	B/Michigan/01/2021 (Victoria Lineage)	5.7×10^6 $TCID_{50}$/mL	1.90×10^3 $TCID_{50}$/mL	9.50×10^1 $TCID_{50}$/Swab	100
	B/Oklahoma/10/2018 (NA D197N (Yamagata Lineage)	7.6×10^7 $TCID_{50}$/mL	7.6×10^4 $TCID_{50}$/mL	3.80×10^3 $TCID_{50}$/Swab	100
	B/Indiana/17/2017 (NA I221T) (Yamagata Lineage)	1.0×10^8 $TCID_{50}$/mL	3.33×10^4 $TCID_{50}$/mL	1.67×10^3 $TCID_{50}$/Swab	100

Co-spike LoD

Following the establishment of single-analyte LoDs for the CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test, co-spike LoD equivalency testing was performed to evaluate the performance in the presence of multiple analytes at low concentrations. Co-spiked samples containing all three target analytes—SARS-CoV-2, Influenza A, and Influenza B—each at their respective single-analyte LoD concentrations was tested in twenty (20) replicates. The co-spiked LoD was confirmed if each analyte yielded at least 95% results agreement, demonstrating co-spike equivalency for all analytes to their respective single-analyte LoDs. The confirmed co-spike LoDs are summarized in Table 4.

Table 4. Confirmed Co-spiked LoDs

Virus Strain	Single-analyte LoD		# of Positive / # of Replicates	Result Agreement (%)
	Titer Unit/mL	Titer Unit/Swab		
Panel I				
SARS-Related Coronavirus 2, Isolate hCoV-19/USA/GA-EHC-2811C/2021, (Lineage B.1.1.529; Omicron Variant	1.5×10^2 $TCID_{50}$/mL	7.50×10^0 $TCID_{50}$/Swab	59/60	98
A/Indiana/02/2020 (H1N1) pdm09	9.7×10^5 $CEID_{50}$/mL	4.85×10^4 $CEID_{50}$/Swab	58/60	97
B/New Hampshire/01/2021 (Victoria Lineage)	4.33×10^2 $TCID_{50}$/mL	2.17×10^1 $TCID_{50}$/Swab	59/60	98
Panel II				
SARS-Related Coronavirus 2, Isolate hCoV-19/USA/GA-EHC-2811C/2021, (Lineage B.1.1.529; Omicron Variant	1.5×10^2 $TCID_{50}$/mL	7.50×10^0 $TCID_{50}$/Swab	59/60	98
A/Hawaii/66/2019 (H1N1) pdm09	7.4×10^6 $CEID_{50}$/mL	3.70×10^5 $CEID_{50}$/Swab	58/60	97
B/Michigan/01/2021 (Victoria Lineage)	1.90×10^3 $TCID_{50}$/mL	9.50×10^1 $TCID_{50}$/Swab	59/60	98

3) Inclusivity (Analytical Reactivity)

The analytical reactivity of the CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test was evaluated using a panel of temporally, geographically, and genetically diverse strains of SARS-CoV-2, Influenza A, and Influenza B. A series of 10-fold dilution was established for each virus strain by spiking the strain into pooled NSM to initially determine the lowest reactive concentration. Following identification of the lowest 10-fold dilution yielding 100% positive results, additional testing was performed using two-fold serial dilutions. The lowest dilution that produced 5/5 positive results was established as the strain-specific detection endpoint and presented in Table 5.

Table 5. Reactivity with SARS-CoV-2, Influenza A and Influenza B Virus Strains

Virus Strain		Lowest Reactive Concentration (Titer Unit/mL)	# of Positive / # of Replicates
SARS-CoV-2	SARS-Related Coronavirus 2 (SARS-CoV-2) Lineage BA.2.12.1	6.30×10^2 $TCID_{50}$/mL	5/5
	SARS-Related Coronavirus 2 (SARS-CoV-2) Lineage BA.2.3	1.17×10^2 $TCID_{50}$/mL	5/5
	SARS-Related Coronavirus 2 (SARS-CoV-2) Lineage BA.2.75.5	8.50×10^1 $TCID_{50}$/mL	5/5
	SARS-Related Coronavirus 2 (SARS-CoV-2) Lineage BA.4.6	5.75×10^2 $TCID_{50}$/mL	5/5
	SARS-Related Coronavirus 2 (SARS-CoV-2) Lineage JN.1.4	2.11×10^2 $TCID_{50}$/mL	5/5
Influenza A	A/Wisconsin/588/2019 (H1N1)pdm09	1.40×10^3 FFU/mL	5/5
	A/Dominican Republic/7293/2013 (H1N1)pdm09	1.25×10^3 $TCID_{50}$/mL	5/5
	A/Massachusetts/15/2013 (H1N1)pdm09	8.00×10^5 $CEID_{50}$/mL	5/5
	A/Bangladesh/3002/2015 (H1N1)pdm09	1.3×10^4 $CEID_{50}$/mL	5/5
	A/Michigan/45/2015 (H1N1)pdm09	7.8×10^2 $TCID_{50}$/mL	5/5
	A/Iowa/53/2015 (H1N1)pdm09	1.45×10^6 $CEID_{50}$/mL	5/5
	A/St. Petersburg/61/2015 (H1N1pdm09)	4.65×10^5 $CEID_{50}$/mL	5/5
	A/Hong Kong/H090-761-V1(0)/2009 (H1N1)pdm09	4.00×10^2 $TCID_{50}$/mL	5/5
	A/Victoria/4897/2022 (H1N1)pdm09	$1.0 \times 10^{6.5}$ EID_{50}/mL	5/5
	A/Victoria/2570/2019 (H1N1)pdm09	$1.0 \times 10^{5.3}$ EID_{50}/mL	5/5
	A/New York/21/2020 (H3N2)	1.30×10^5 FFU/mL	5/5
	A/Michigan/173/2020 (H3N2)	1.95×10^5 FFU/mL	5/5
	A/Tasmania/503/2020 (H3N2)	6.50×10^4 FFU/mL	5/5
	A/Texas/50/2012 (H3N2)	8.75×10^3 $TCID_{50}$/mL	5/5
	A/Switzerland/9715293/2013 (H3N2)	6.00×10^5 $CEID_{50}$/mL	5/5
	A/Hong Kong/4801/2014 (H3N2)	9.6×10^5 $CEID_{50}$/mL	5/5
	A/Singapore/INFIMH-16-0019/2016 (H3N2)	5.50×10^4 $CEID_{50}$/mL	5/5
	A/Perth/16/2009 (H3N2)	1.1×10^5 $CEID_{50}$/mL	5/5
	A/Darwin/9/2021 (H3N2)	$1.0 \times 10^{4.3}$ EID_{50}/mL	5/5
	A/Georgia/02/2022 (H3N2)	$5.00 \times 10^{5.5}$ EID_{50}/mL	5/5
	A/bovine/Ohio/B24OSU-439/2024 (H5N1)	3.1×10^2 $TCID_{50}$/mL	5/5
Influenza B	B/Texas/43/2019 (Victoria Lineage)	5.0×10^2 $TCID_{50}$/mL	5/5
	B/Washington/02/2019 (Victoria Lineage)	2.1×10^6 $CEID_{50}$/mL	5/5
	B/Brisbane/60/2008 (Victoria Lineage)	5×10^3 $CEID_{50}$/mL	5/5
	B/Austria/1359417/2021 (Victoria Lineage)	$5.00 \times 10^{4.5}$ EID_{50}/mL	5/5
	B/Netherlands/10894/2022 (Victoria Lineage)	$1.0 \times 10^{4.7}$ EID_{50}/mL	5/5
	B/Phuket/3073/2013 (Yamagata Lineage)	2.75×10^4 $CEID_{50}$/mL	5/5

Virus Strain		Lowest Reactive Concentration (Titer Unit/mL)	# of Positive / # of Replicates
	B/Wisconsin/10/2016 (NA I221V) (Yamagata Lineage)	3.2×10^5 $TCID_{50}$/mL	5/5
	B/Texas/06/2011 (Yamagata Lineage)	1.6×10^5 $CEID_{50}$/mL	5/5
	B/Phuket/3073/2013 (Yamagata Lineage)	$1.0 \times 10^{3.8}$ EID_{50}/mL	5/5
	B/Norway/2134/2019 (Yamagata Lineage)	$2.5 \times 10^{4.5}$ EID_{50}/mL	5/5

4) Competitive Interference

The competitive interference study was conducted to assess whether the presence of a high concentration of one target analyte interferes with the detection of other target analytes in the CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test. The study evaluated potential cross-analyte inhibition using contrived samples containing various combinations of SARS-CoV-2, Influenza A, and Influenza B at predefined low and high concentrations. Low concentration samples were prepared at 3× the established Limit of Detection (LoD) for each analyte. High concentration samples were prepared at $\geq 1.0 \times 10^5$ $TCID_{50}$/mL or $CEID_{50}$/mL, depending on the virus type. A panel of 19 sample configurations was tested in triplicate. All target analytes at low concentrations were detected with 100% agreement, regardless of the presence of high concentrations of other analytes. No evidence of competitive interference was observed in any tested panel. A summary of the panel configurations and corresponding results is presented in Table 6.

Table 6. Sample Panel and Competitive Interference Results

No.	Target Analyte in Sample (Concentration)			Result Agreement (%)
	SARS-CoV-2	Influenza A	Influenza B	
1	-	High	Low	100
2	Low	High	-	100
3	Low	High	Low	100
4	-	Low	High	100
5	Low	-	High	100
6	Low	Low	High	100
7	High	Low	-	100
8	High	-	Low	100
9	High	Low	Low	100
10	Low	High	High	100
11	High	High	Low	100
12	High	Low	High	100
13	-	High	High	100
14	High	High	-	100
15	High	-	High	100
16	High	High	High	100
17	-	High	-	100
18	-	-	High	100
19	High	-	-	100

5) Hook Effect Study

A high-dose hook effect study was conducted to determine whether excessive concentrations of SARS-CoV-2, Influenza A, or Influenza B antigens interfere with the detection performance of the CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test. Each analyte was tested individually across a series of 2-fold serial dilutions using inactivated SARS-CoV-2, live Influenza A, and live Influenza B strains spiked into a pooled NSM. All samples were tested in five replicates and the results yielded 100% positive result agreement with no false negative results indicating no hook effect observed at elevated antigen concentrations. A summary of hook effect study results is provided in Table 7.

Table 7. Summary of Hook Effect Study Results

Virus Strain	Testing Concentration (Titer Unit/mL)	Result Agreement(%)
SARS-Related Coronavirus 2, Isolate USA-WA1/2020	3.95×10^5 $TCID_{50}$/mL	100
SARS-Related Coronavirus 2, Isolate hCoV-19/USA/GA-EHC-2811C/2021 (Lineage B.1.1.529; Omicron Variant)	7.50×10^5 $TCID_{50}$/mL	100
Influenza A, A/Indiana/02/2020 (H1N1) pdm09	4.85×10^8 $CEID_{50}$/mL	100
Influenza A, A/Delaware/01/2021 (H3N2)	1.55×10^7 FFU/mL	100
Influenza B, B/New Hampshire/01/2021 (Victoria Lineage)	6.50×10^5 $TCID_{50}$/mL	100
Influenza B, B/Indiana/17/2017 (NA I221T) (Yamagata lineage)	5.00×10^7 $TCID_{50}$/mL	100

6) Analytical Sensitivity (1st WHO International Standard for SARS-CoV-2 Antigen)

The analytical sensitivity of the CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test was evaluated using the 1st WHO International Standard for SARS-CoV-2 Antigen (NIBSC code: 21/368). To determine the preliminary Limit of Detection (LoD), a 5-fold serial dilution starting from 4000 IU/mL was prepared and tested in triplicate. The preliminary LoD concentration was then confirmed by testing twenty (20) replicates. The final LoD using the WHO standard is presented in Table 8.

Table 8. LoD for 1st WHO International Standard for SARS-CoV-2 Antigen

SARS-CoV-2 Antigen	LoD		# of Positive / # of Replicates	Result Agreement (%)
	IU/mL	IU/Swab		
WHO Standard (NIBSC 21/368)	160	8	19/20	95

7) Cross Reactivity/Microbial Interference Study

To evaluate the potential cross-reactivity and microbial interference of the CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test, 27 microorganisms, including viruses, bacteria, yeast, and representative respiratory flora commonly found in nasal specimens. Each microorganism was tested in triplicate both in the absence and presence of the target analytes—SARS-CoV-2, Influenza A, and Influenza B. Analyte-negative samples were prepared using pooled NSM, while analyte-positive samples were contrived by spiking NSM with all three analytes at 3X the co-spike limit of detection. No cross-reactivity or microbial interference was observed with any of the tested microorganisms. All analyte-negative samples produced negative results, and all analyte-positive samples demonstrated 100% agreement with expected positive results. A summary of the cross reactivity and microbial interference results is provided in Table 9.

Table 9. Summary of Cross-reactivity and Microbial Interference Results

Microorganism/Virus	Testing Concentration	Cross-Reactivity (Yes/No)	Microbial Interference (Yes/No)
Adenovirus 1	1.58×10^5 $TCID_{50}$/mL	No	No
Adenovirus 7	1.6×10^5 $TCID_{50}$/mL	No	No
Enterovirus 71, Tainan/4643/1998	1.6×10^6 $TCID_{50}$/mL	No	No
Human coronavirus (OC43)	1.4×10^5 $TCID_{50}$/mL	No	No

Microorganism/Virus	Testing Concentration	Cross-Reactivity (Yes/No)	Microbial Interference (Yes/No)
Human coronavirus (229E)	1.4 x 10^4 $TCID_{50}$/mL	No	No
Human coronavirus (NL63)	8.0 x 10^4 $TCID_{50}$/mL	No	No
Human metapneumovirus (hMPV)	2.8 x 10^5 $TCID_{50}$/mL	No	No
MERS-Coronavirus, Irradiated Lysate	1.78 x 10^5 $TCID_{50}$/mL	No	No
Parainfluenza virus type 1	7.4 x 10^5 $TCID_{50}$/mL	No	No
Parainfluenza virus type 2	1.58 x 10^5 $TCID_{50}$/mL	No	No
Parainfluenza virus type 3	1.58 x 10^5 $TCID_{50}$/mL	No	No
Parainfluenza virus type 4	5.0 x 10^5 $TCID_{50}$/mL	No	No
Respiratory syncytial virus Type B	1.58 x 10^5 $TCID_{50}$/mL	No	No
Rhinovirus	1.58 x 10^5 $TCID_{50}$/mL	No	No
SARS-Coronavirus	1.0 x 10^5 PFU/mL	No	No
Human coronavirus HKU1* (clinical specimen)	N/A	No	No
Bodetella pertussis	1.0 x 10^7 CFU/mL	No	No
Chlamydophila pneumoniae	1.4 x 10^6 IFU/mL	No	No
Haemophilus influenzae	1.6 x 10^6 CFU/mL	No	No
Legionella pneumophila	1.35 x 10^6 CFU/mL	No	No
Mycoplasma pneumoniae	6.5 x 10^5 CFU/mL	No	No
Streptococcus pneumoniae	1.0 x 10^7 CFU/mL	No	No
Streptococcus pyogenes, Group A	1.0 x 10^7 CFU/mL	No	No
Staphylococcus aureus	1.0 x 10^7 CFU/mL	No	No
Staphylococcus epidermidis	1.0 x 10^7 CFU/mL	No	No
Candida albicans	1.0 x 10^7 CFU/mL	No	No
Pooled human nasal wash – representative of normal respiratory microbial flora	N/A	No	No

*10-fold dilution of the stock Human Coronavirus HKU1 (HCoV-HKU1) clinical sample was tested in triplicates in the presence and absence of SARS-CoV-2. The Ct value of the undiluted sample was 11.7.

8) Endogenous and Exogenous Substances Interference Study

The potential interference of endogenous and exogenous substances with the CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test was evaluated using 43 substances commonly present in respiratory specimens, including over-the-counter (OTC) nasal sprays, throat lozenges, prescription medications, homeopathic remedies, and biological components such as whole blood, buffy coat, mucin, and leukocytes. Each substance was tested in triplicate both in the absence and presence of the target analytes—SARS-CoV-2, Influenza A, and Influenza B—at 3X the established co-spike LoD. Analyte-negative samples were prepared by mixing each substance with pooled NSM, while analyte-positive samples were co-spiked with the target viruses and then mixed with the substances. No cross-reactivity or interference was observed; all target analytes were accurately detected in the presence of the potentially interfering substances, and no false-positive results were observed in their absence. A summary of the endogenous and exogenous substances interference results is provided in Table 10.

Table 10. Summary of Endogenous and Exogenous Substances Interference Results

Substance	Testing Concentration	Cross-Reactivity (Yes/No)	Interference (Yes/No)
Acetaminophen	10 mg/mL	No	No
Acetyl salicylic acid	15 mg/mL	No	No

Substance	Testing Concentration	Cross-Reactivity (Yes/No)	Interference (Yes/No)
Beclomethasone	5 mg/mL	No	No
Benzocaine	5 mg/mL	No	No
Budesonide	2 mg/mL	No	No
Chlorpheniramine maleate	5 mg/mL	No	No
Dexamethasone	1 mg/mL	No	No
Dextromethorphan HBr	2 mg/mL	No	No
Diphenhydramine HCl	5 mg/mL	No	No
Flunisolide	5 mg/mL	No	No
Fluticasone	1 mg/mL	No	No
Guaiacol Glyceryl Ether	20 mg/mL	No	No
Histamine Dihydrochloride	10 mg/mL	No	No
Menthol	10 mg/mL	No	No
Mometasone	1 mg/mL	No	No
Molnupiravir	1 mg/mL	No	No
Mucin (Bovine submaxillary glands -Type I-S)	2.5 mg/mL	No	No
Mupirocin	1 mg/mL	No	No
	10 mg/mL	No	No
Phenylpropanolamine	5 mg/mL	No	No
Remdesivir	1 mg/mL	No	No
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	No	No
Tobramycin	1 mg/mL	No	No
Triamcinolone	1 mg/mL	No	No
Zanamivir	1 mg/mL	No	No
Sore Throat Spray (Phenol)	15 % v/v	No	No
Zicam Oral Mist (Zincum aceticum, Zincum gluconicum)	15 % v/v	No	No
Nasal Spray (Phenylephrine HCl)	15 % v/v	No	No
NasalCrom Nasal Spray (Cromloyn sodium)	15 % v/v	No	No
Vicks Sinex Nasal spray (Oxymetazoline HCl)	15 % v/v	No	No
Alkalol Allergy Relief (Galphimia glauca, Luffa operculate, Sabadilla)	15 % v/v	No	No
Zicam Allergy Relief (Galphimia glauca, Histaminum hydrochloricum, Luffa operculate, Sulphur)	15 % v/v	No	No
Hand Sanitizer	15 % v/v	No	No
Hand Soap	15 % v/v	No	No
Whole blood	2.5 % v/v	No	No
Buffy coat	2.5 % v/v	No	No
Allergy Spray (Mometasone Furoate)	15 % v/v	No	No
Budesonide Nasal Spray (Budesonide/Glucocorticoid)	15 % v/v	No	No
Nasacort Allergy 24HR (Triamcinolone acetonide)	15 % v/v	No	No
Allergy Relief Nasal Spray (Fluticasone Propionate)	15 % v/v	No	No
Saline Nasal Spray (Sodium Chloride & Preservatives)	15 % v/v	No	No

Substance	Testing Concentration	Cross-Reactivity (Yes/No)	Interference (Yes/No)
Alkalol Saline Nasal Spray (Sodium Chloride, Menthol, Thymol, Camphor, Benzoin Resin Extract, Oils of Eucalyptus, Wintergreen, Spearmint, Fir Needle, Cinnamon & Preservatives)	15 % v/v	No	No
Leukocytes	5.0 x 10^6 cells/mL	No	No
Zinc Throat Spray (Thera Zinc Throat Spray)	15 % v/v	No	No

9) Biotin Interference

A biotin interference study was conducted to assess the impact of elevated biotin (vitamin B7) concentrations on test performance. Serial dilutions of biotin (5,000 to 0 ng/mL) were tested in triplicate using both analyte-negative and analyte-positive samples (3X LoD co-spiked SARS-CoV-2, Influenza A, and Influenza B). No false positives were observed at any concentration. However, false negatives were observed for Influenza A at 3,750 ng/mL and 5,000 ng/mL. A summary of biotin interference study is provided in Table 11.

Table 11. Biotin Interference Study Summary

Biotin Concentration (ng/mL)	# of Positive / # of Replicates			
	SARS-CoV-2	Influenza A	Influenza B	Negative (Analyte-absent)
5,000	3/3	0/3	3/3	0/3
3,750	3/3	0/3	3/3	0/3
2,500	3/3	3/3	3/3	0/3
1,250	3/3	3/3	3/3	0/3
625	3/3	3/3	3/3	0/3
312.5	3/3	3/3	3/3	0/3
0	3/3	3/3	3/3	0/3

10) Realtime Stability

A real-time stability study was conducted to evaluate the shelf-life of the CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test under labeled storage conditions. Three product lots were stored at 2 °C and 30 °C/80% relative humidity, with monthly testing conducted over 15 months. At each time point, five replicates per lot were tested using contrived positive samples spiked with SARS-CoV-2, Influenza A, and Influenza B at 4X the co-spike LoD and confirmed negative samples (natural clinical anterior nasal swab matrix). Across all tested time points and storage conditions, 100% of the replicates yielded expected results with no false positives or false negatives observed. The test kits demonstrated consistent performance supporting a claimed shelf-life of 13 months. The study is ongoing to confirm extended stability and will continue until nonconforming results are observed.

11) Transportation Stability

The transportation stability study evaluated the performance of the CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test following exposure to simulated extreme shipping conditions. Test kits from three product lots were incubated for ten consecutive days under high-temperature and high-humidity conditions (60°C and 85% relative humidity) to simulate summer transport, and under freezing conditions (–20°C) to simulate winter transport. At each daily interval, test performance was assessed using contrived positive samples containing SARS-CoV-2, Influenza A, and Influenza B antigens at 4X the co-spike LoD and confirmed negative samples prepared using a pooled NSM. Each condition was tested in five replicates per sample type per lot. All results were consistent with expected outcomes and no false positives or false negatives were observed under the tested condition.

12) Clinical Performance

The clinical performance characteristics of the CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test was evaluated in symptomatic subjects, suspected of respiratory infection at 13 clinical sites across the U.S. between November of 2023 and March of 2025. Two anterior nasal swab specimens were collected in randomized order from each participant: one swab was self-collected and immediately tested with the CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test in a simulated home-use setting by participants and the other swab sample was collected by healthcare professional for testing using FDA-cleared molecular RT-PCR comparator assays for SARS-CoV-2, and Influenza A and Influenza B. The CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test demonstrated the following clinical agreement with the molecular comparator methods.

Table 12. Subject Demographics

Characteristic	Self-Collecting (N=1447)	Lay-user/ Tester Collection (N=197)	Overall (N=1644)
Age			
Mean (SD)	42.0 (17.2)	7.6 (3.7)	37.8 (19.8)
Median [Min, Max]	41 [13, 90]	7.5 [2, 17]	37 [2, 90]
Age Group			
2-13	1	192	193
14-24	267	5	272
25-64	1025	0	1025
>64	154	0	154
Sex at Birth			
Female	842	104	946
Male	605	93	698
Ethnicity			
Hispanic or Latino (of any race)	635	74	709
Not Hispanic or Latino	806	116	922
Unknown	6	7	13
Race			
American Indian or Alaskan Native	6	1	7
Asian	91	13	104
Black or African American	208	16	224
Native Hawaiian or Other Pacific Islander	14	2	16
More Than One Race	31	11	42
Prefer Not to Answer	1	0	1
Unknown	16	12	28
White	1080	142	1222

Table 13. Performance Compared to SARS-CoV-2 Molecular Assay

CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test	Comparator		
	Positive	Negative	Total
Positive	111	6	117
Negative	9	1518	1527
Total	120	1524	1644
Positive Percent Agreement (PPA)	92.5% (111/120) (95% CI:86.4%-96.0%)		
Negative Percent Agreement (NPA)	99.6% (1518/1524) (95% CI:99.1%-99.8%)		

Table 14. SARS-CoV-2 Performance Stratified by Days Post Symptoms Onset (DPSO)

DPSO	# of Subject Samples Tested	CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test Positives	Comparator Positives	PPA
Day 0	24	N/A	N/A	N/A
Day 1	226	16	18	88.9%
Day 2	567	44	47	93.6%
Day 3	553	35	36	97.2%
Day 4	274	16	19	84.2%
Total	1644	111	120	92.5%

Table 15. Performance Compared to Influenza A Molecular Assay

CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test	Comparator		
	Positive	Negative	Total
Positive	95	15	110
Negative	16	1491	1507
Total	111	1506	1617
Positive Percent Agreement (PPA)	85.6% (95/111) (95% CI:77.9%-90.9%)		
Negative Percent Agreement (NPA)	99.0% (1491/1506) (95% CI:98.4%-99.4%)		

Table 16. Performance Compared to Influenza B Molecular Assay

CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test	Comparator		
	Positive	Negative	Total
Positive	37	5	42
Negative	6	1568	1574
Total	43	1573	1616
Positive Percent Agreement (PPA)	86.0% (37/43) (95% CI:72.7%-93.4%)		
Negative Percent Agreement (NPA)	99.7% (1568/1573) (95% CI:99.3%-99.9%)		

13) Usability Study

A usability study was conducted to evaluate the performance of intended users in conducting the CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test by assessing the ability of individuals aged 14 and older, as well as adults testing children aged 2 and above, to correctly perform the test and interpret the results in a home setting. Among 1,795 participants representing the lay population, over 98% completed each critical test step correctly, including sample collection, buffer addition, swab handling, timing, and result interpretation. Observer agreement with user-interpreted results was 98.7%. Questionnaire responses indicated that more than 94% of users found the instructions easy to understand and the test simple to perform. The study demonstrated that individuals without training can safely and effectively use the CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test as intended and the product instruction was found to be clear and accessible across the intended population.

14) Readability Study

A readability study was conducted to evaluate whether untrained lay users could understand the Quick Reference Instruction (QRI) and correctly interpret test results for the CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test. Fifty participants aged 14 and older, with diverse educational backgrounds and no medical or laboratory training, were enrolled and asked to interpret ten mock test devices after reading the QRI, without any prior training. The study simulated a home-use environment and included users with and without visual impairments. Out of 500 total device interpretations, 474 (94.8%) were correctly interpreted without assistance. The study concluded that intended users were able to understand the labeling and interpret both positive and negative results accurately.

8. Conclusion

The information provided in this Premarket Notification (510(k)) supports the substantial equivalency of the CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test to the predicate device, WELLlife™ COVID-19 / Influenza A&B Home Test and WELLlife™ COVID-19 / Influenza A&B Antigen Test in technological and performance characteristics and intended use.